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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,061	02/20/2004	Vincent Sullivan	035510/303994(P-5972)	6766
47656 7590 09/11/2007 BECTON, DICKINSON AND COMPANY (ALSTON & BIRD LLP) 1 BECTON DRIVE MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER TONGUE, LAKIA J	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 09/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,061	SULLIVAN ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71 and 76-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71 and 76-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed on June 25, 2007 is acknowledged. Claims 71 and 76-80 are pending and under consideration. Claim 71 has been amended. Claims 69, 70 and 72-75 have been canceled. Claims 76-80 have been newly added. Claims 71 and 76-80 are under examination.

Objections Withdrawn

1. In view of Applicant's amendment to the specification the objection to the specification for the use of the trademark Accuspray is withdrawn.
2. In view of Applicant's amendment to claim 71 the objection to claim 71 for misspelling the word staphylococcal is withdrawn.

Rejections Withdrawn

3. In view of Applicant's cancellation of claim 69 the rejection of claims 69 and 71 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, particularly claim 69, which was rendered vague and indefinite by the use of the term "therapeutic" is withdrawn.

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4. In view of Applicant's cancellation of claim 69 the rejection of claim 69 under 35 U.S.C. 102(b) as being anticipated by Ahmed et al. (Microbiol. Immunol., 1994; 38(11): 837-842) is withdrawn.
5. In view of Applicant's cancellation of claim 69 the rejection of claim 69 under 35 U.S.C. 102(b) as being anticipated by Terman (U.S. Patent 6,251,385 B1) is withdrawn.
6. In view of Applicant's cancellation of claim 69 and in lieu of the rejection set forth below the rejection of claims 69 and 71 under 35 U.S.C. 102(e) as being anticipated by Sasaki et al. (U.S. 2006/0024322 A1) is withdrawn.
7. In view of Applicant's cancellation of claim 69 the rejection of claim 69 under 35 U.S.C. 102(e) as being anticipated by Hwang et al. (U.S. 2003/0186271 A1) is withdrawn.
8. In view of Applicant's cancellation of claim 69 the rejection of claim 69 under 35 U.S.C. 102(e) as being anticipated by Hwang et al. (U.S. 2003/0180755 A1) is withdrawn.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 71 and 76-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maa et al. (U.S. 2002/0120228 A1) further in view of Sasaki et al. (U.S. 2006/0024322 A1).

The instant claims are drawn a particulate recombinant Staphylococcal enterotoxin B (rSEB) vaccine composition made by the method comprising: atomizing a liquid rSEB formulation to produce an atomized formulation, freezing said atomized rSEB formulation to form solid particles, and drying said solid particles to produce discrete dried particles of said rSEB vaccine composition.

Maa et al. disclose a particulate composition made by a method comprising atomizing the suspended vaccine composition into liquid nitrogen, which acts as a heat transfer agent and provides rapid freezing of the suspension. The atomization reduces the volume of each droplet to be frozen and the combined effect causes extreme freezing of very small droplets of suspension and leads to the formation of smaller ice crystals in the solid (see paragraph 0015). Moreover, Maa et al. disclose that any suitable antigen may be employed. The antigen may be viral or bacterial antigens derived from organisms that cause, for instance, Staphylococcus (see paragraphs 0091

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and 0093). Maa et al. further disclose that the particles of the invention have a size appropriate for high-velocity delivery to a subject. The mass mean aerodynamic diameter of the particles is from about 0.1 to 250 μm , preferably from 10 to 70 μm or from 20 to 70 μm (see paragraph 0103). The instant specification discloses that the claimed method and composition made by the method are referred to as "spray-freeze-dried" (see specification at page 7, lines 1 and 2). Maa et al. disclose that the method and composition made by the method are referred to as "spray-freeze-dried", therefore the limitations of "having a volume mean diameter of 35 μm and about 300 μm ; 50 μm and about 100 μm , and at least about 50% of said discrete dried particles have a volume diameter with in about 80% of the mean would necessarily be met because the compositions are identical and are produced by the same method step.

Maa et al. does not specifically disclose that the composition is a recombinant Staphylococcal enterotoxin B vaccine composition.

Sasaki et al. disclose recombinant Staphylococcal enterotoxin B (SEB) formulated into prophylactic remedies. Sasaki et al. disclose that the vaccine may be in a lyophilized form (see paragraph 0048).

Thus, it would have been obvious to one having ordinary skill in the art to use recombinant Staphylococcal enterotoxin B as taught by Sasaki et al. because it is a well-known bacterial super antigen which provides prophylactic remedies because of its inhibitory activity on T cell activation (see Sasaki et al., paragraph 0004) as shown in Maa et al., which discloses that antigens can be isolated directly from whole killed, attenuated or inactivated bacteria, viruses, parasites or other microbes may be

employed, as well as be produced recombinantly using known techniques (see Maa et al. paragraph 0094). Since the compositions are the same they would necessarily have the same immunological results.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
8/29/07



ROBERT A. ZEMAN
PRIMARY EXAMINER